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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,734	06/14/2000	SILVIU ITESCU	31856-PCT	2918

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/13/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

509734

Applicant(s)

ITESCU

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/25/02 & 5/30/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
- Of the above claim(s) 8-18 is/are withdrawn from consideration.
- ☒ Claim(s) 1-7 is/are allowed.
- ☒ Claim(s) 19 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Amendments of 11/25/02 and 5/30/03 have been entered.

Claims 1-19 are pending; claims 1-7 and 19 are under examination.

Applicant is reminded of the requirement for submission of the abstract on a separate sheet.

Applicant's amendment has overcome 112, second paragraph issues of record.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite by reciting "a panel of control B lymphocytes" since one does not know what factors/variables these "control" for in the methods.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 contains new matter because recitation of merely "a panel of control B lymphocytes" is overly broad in comparison to "B lymphocytes obtained from a panel of control individuals representative of the most frequently encountered HLA class I and class II antigen in the general population" (see page 10, lines 15-17 and lines 30-31; see page 28, lines 17-19). It is also new matter per applicant to test only against a B-cell panel and not against both B and T panels.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 19 is not enabled because, from applicant's own disclosure, it appears that two control panels of B- and of T- lymphocytes are needed and that one determines DR (class II) reactivity by virtue of obtaining ^a ratio of reactivity against B-versus T- lymphocytes. See page 10, lines 22-23; page 11, lines 13-17; page 29 lines 7-18.

Claim 19 is rejected under 35 U.S.C. 102(a) as being entirely anticipated by Itescu et al (circulation, 98, 786, 1998), for reasons of record.

Applicant has urged that provisional application 60/090,153, which predates Itescu et al, supports claim 19 at page 12. This disclosure does not, when claim 19 is read with the proper hindsight.

Claim 19 recites (line 1) "a transplant recipient" which term is properly taken to encompass both pre-and post-transplant recipients, as contemplated by applicant at instant page 15. Also, instant Example 7, upon which claim 19 is based, detects IgG antibodies in pre-transplant individuals. Nothing the '153 application refers to detecting the antibodies in pre-transplant patients, at page 12 or anywhere else. Since the '153 application cannot support the full breadth of applicant's claim, the claim cannot be granted benefit of the filing date of the '153 provisional application. Additionally one of skill reading the '153 application would not have appreciated that merely detecting IgG antibodies per se amounted to a useful method since the disclosure concludes with a

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teaching^{of} a consideration of the three-factor algorithm, akin to that of instant claim 1 (not rejected).

Applicant's urgings filed 11/25/02 have been considered but are unconvincing.

Due to applicant's amendment of claim 19 the previously stated 102 rejection over Ten-Hoor et al has been withdrawn. The claim calls for testing against a panel^{el} of cells; the reference teaches testing against donor cells. The results obtained by testing for antibody reactivity against a panel of cells (PRA) and the results obtained by testing against donor cells do not necessarily correlate. See George et al (IDS ref.20), page 856 under "conclusions". See Smith et al (IDS ref. 21), in the abstract. There is therefore no basis for making a 103 rejection by combining Ten Hoor et al with a reference teaching PRA testing.

Due to applicant's urgings the previously stated 102/103 rejection over Lazda has been withdrawn. The examiner also notes that Lazda teaches testing for crossmatching antibody reactivity against donor cells, rather than against a panel of cells.

Applicant's amendment of claim 19 and late submission of a new IDS have necessitated the following new ground of rejection over the prior art.

Claim 19 is rejected under 35 U.S.C. 102(b) as entirely anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Itescu et al (Journal Heart Lung Transplant., 16, 78, 1997).

Itescu et al test for the presence of IgG anti-class II and IgG anti-class I antibodies in pre-transplant sera of patients. They teach that their results were obtained

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by reactivity against a panel of allogeneic B and T-cells (note recitation of PRA). Their conclusions indicate that IgG anti-class II antibodies confer the highest risk for rejection. If not anticipated, applicant's invention would have, at the least would have been obvious from these conclusions.

This application contains claims 8-18 are drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

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(703) 308-3976. The examiner can normally be reached on Monday-Thursday 8 am -
5:30 pm ^{and on} Alternative Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/tgd
August 11, 2003

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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